REMARKS

By the present amendment, claims 1, 2, 20-22, 39, 41, 47-49, 51-52 and 56 have been amended, and claims 3-10, 15-16, 18-19, 23-29, 31-38, 40, 42-46, 50, and 53 have been cancelled. The claims have been amended to specify the candidate polypeptide is prion polypeptide, the target epitope is recognized by an antibody designated as 3F4 and/or an antibody designated as 6H4 and to specify the blocking agent is peroxynitrite as discussed below.

The Applicant has also amended the specification and the sequence listing to correct an obvious error. The epitope recongized by 3F4 was incorrectly identified as "MKHV" at pages 38 and 64. The actual epitope recognized by 3F4 as was known at the time of filing is MKHM. Bolton et al., J Virol (1991), p3667-3675 (previously submitted on an IDS dated July 11, 2006, cite no. 1), demonstrates that an epitope recognized by 3F4 is MKHM. The Applicant respectfully submits that the error was an inadvertant error that a person skilled in the art would readily recognize as an obvious error.

Sequence Listing

In order to comply with the requirements of 37 C.F.R. 1.824(a)(2)-(6) and (b) Applicants are submitting herewith (using the EFS online filing system) a Sequence Listing in computer readable form in the text format only.

The amendments to the claims have been made without prejudice. Applicant reserves the right to pursue any of the deleted subject matter in a further divisional, continuation or continuation-in-part application. The Applicant submits that the amendment does not include new matter which goes beyond the disclosure of the application as filed and its entry is respectfully requested.

The Office Action dated December 29, 2009 has been carefully considered. It is believed that the claims submitted herewith and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

Claim Objections:

The Examiner has objected to claims 1, 39, 49 and 56 for an allegedly missing "an" article in each of these claims.

The claims have been amended to introduce "an" as suggested by the Examiner. In light of the above, the Applicant respectfully requests that the objection to the claims be withdrawn.

35 USC § 112, first paragraph

The Examiner has maintained the objection to claims 1-2, 9, 11-14, 16-17, 20-22, 29-30, 39, 41, 47-49 and 51-56 alleging, the specification while enabling for detecting epitopes recognized by antibodies 6H4 and 3F4 in prion protein PrP, does not reasonably provide enablement for the claimed method of detecting whether a structurally and functionally defined candidate polypeptide with an unknown target epitope is in a wildtype or non-wildtype conformation by using an unknown chemical modifying agent to block an unknown accessible epitope in the polypeptide, disaggregating or denaturing the candidate protein, and determining whether the modified protein is a wildtype or non-wildtype conformation as broadly claimed.

In order to expedite prosecution, the Applicant has cancelled claims 9, 16, 29 and 53 and has amended the claims to specify a prion polypeptide including a target epitope, wherein the target epitope is recognized by an antibody designated as 3F4 and/or an antibody designated as 6H4, and to replace "chemical modifying agent" with peroxynitrite. Exemplary support is provided for example in Example 2.

In light of the above, the Applicant respectfully submits that the specification is enabling for the present claims and respectfully requests that the objections to the claims under 35 USC §112 first paragraph for lack of enablement be withdrawn.

35 USC §112 first paragraph

The Examiner has rejected claims 1-2, 9, 11-14, 16-17, 20-22, 29-30, 39, 41, 47-49 and 51-56 as failing to comply with the written description requirement.

As mentioned, the Applicant has cancelled claims 9, 16, 29 and 53 and has amended the remaining claims to specify a prion polypeptide including a target epitope, wherein the target epitope is recognized by an antibody designated as 3F4 and/or an antibody designated as 6H4, and to replace "chemical modifying agent" with peroxynitrite. Written description for the presently claimed embodiments is found throughout and for example at pages 8 and 16 and in Example 2.

In light of the above, the Applicant respectfully requests that the rejection to the claims for failing the written description requirement, be withdrawn.

Double patenting

The Examiner has rejected claims 1, 2, 9, 11-14, 16-17, 20-22, 29-30, 39, 41, 47-49 and 51-56 on the ground of non-statutory obviousness type double patenting over claims 18-22 of US Patent No 7041807 (Cashman '807). The Examiner suggests that the claims of Cashman '807 "are directed to a method for detecting PrPSc in a biological sample using an antibody that is able to recognize PrPSc wherein the antibody selectively binds to PrPSc". From this statement the Examiner concludes that the '807 patent is a species that anticipates the generic claimed method "because the claimed method is directed to a method of detecting all forms of polypeptides including PrPSc using all forms of detecting agents including antibodies against PrPSc. In addition since the instant claims do not limit the blocking agent used in the claimed method, any agent including the antibody in '807 meets the limitation of blocking agent and thus anticipates the claims".

The Applicant respectfully disagrees. However, in order to advance prosecution the Applicant has amended the claims as mentioned above, for example to replace "chemical modifying agent" with peroxynitrite. The claims in Cashman '807 do not

embrace the step of reacting peroxynitrite with a target epitope. Accordingly, the Applicant respectfully submits that the claims in Cashman '807 are patently distinct.

In light of the above the Applicant respectfully requests that the double patenting rejection to all the claims be withdrawn.

35 USC § 102

The Examiner has maintained the rejection to claims 1-2, 9, 11-14, 16-17, 20-22, 29-30, 39, 41, 47-49 and 51-55 as being anticipated by US2002/0123072 (Prusiner) and US 6677125 (Prusiner). Specifically the Examiner alleges "Prusiner teaches a method of detecting the presence of a disease related to conformation of a protein PrPSc (non-wildtype conformation) and a non-disease related conformation of the protein (PrPc (wildtype conformation) in a sample using an antibody specific for PrPSc", which the Examiner alleges meets the limitations as recited in the objected to claims.

As mentioned, the Applicant has amended the claims to replace "chemical modifying agent" with peroxynitrite. Prusiner relies on digestion. As the instant specification teaches at page 12: "epitope protection technology does not require a protease digestion step, which makes it more sensitive to early infection. Certainly, the absence of a protease digestion step permits EPA to be more amenable to high-throughput robotic platforms." Further, the Prusiner application and patent do not disclose reacting peroxynitrite with a target epitope. Accordingly, the Applicant respectfully submits that Prusiner application and patent do not anticipate the objected to claims as amended.

The Examiner has maintained the rejection of claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 as being anticipated by US 7041807 (Cashman). The Examiner alleges that Cashman teaches a method for detecting PrPSc in a biological sample using an antibody that is able to recognize PrPSc wherein the antibody selectively binds to PrPSc.

Although the Applicant respectfully disagrees, the claims have been amended to claim contacting the prion polypeptide with "peroxynitrite" which is not disclosed by Cashman '807. Accordingly, the Applicant respectfully submits that Cashman '807 cannot anticipate the objected to claims.

In light of the above, the Applicant respectfully requests that the objections to the claims under 35 USC §102 be withdrawn.

In view of the foregoing, we respectfully submit that the application is in order for allowance and early indication of that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater detail, he/she is kindly requested to contact Carmela DeLuca at her convenience.

The Commissioner is hereby authorized to charge any deficiency in fees or credit any overpayment to our Deposit Account No. 02-2095

Respectfully submitted,

Bereskin & Parr LLP/S.E.N.C.R.L., s.r.l

By 

Carmela DeLuca
Reg. No. 61,772
Tel: (416) 957-1619